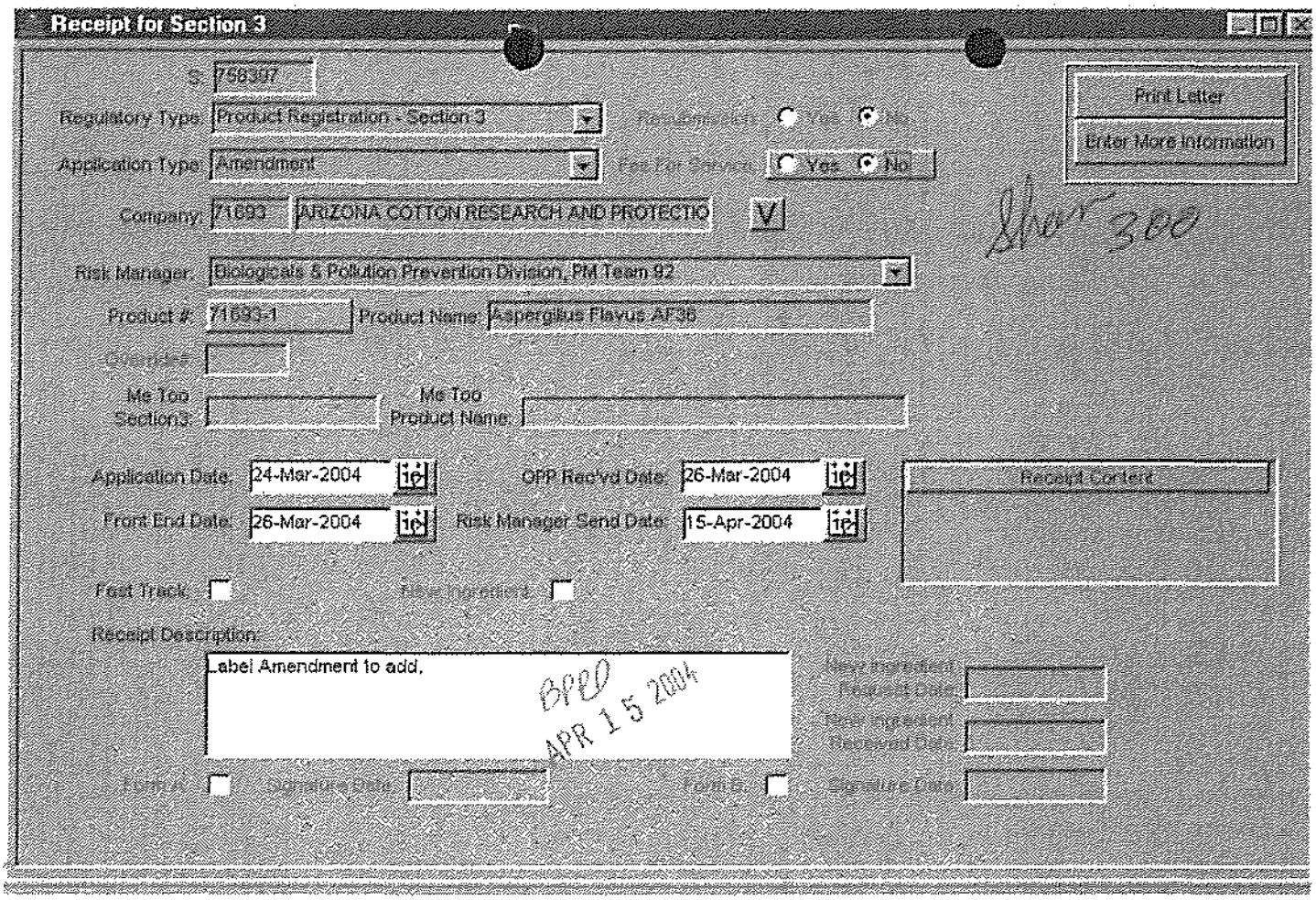
EPA REGISTRATION NUMBER 71693-1 – VOLUME 5



758397 | 300

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AIO
APR 21 2004
sdh

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA — United States Environmental Protection Agency, Washington, DC 20460

☐ Registration ☑ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
AZ Cotton Research and Protection Council 71693-1.	Shanaz Bacchus	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
Aspergillus flavus AF36		

5. Name and Address of Applicant (Include ZIP Code)

Arizona Cotton Research and Protection Council
3721 E. Weir Avenue
Phoenix, Arizona 85040-2933

☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
This is a label amendment to add California to the label

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☐ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) Bulk boxes, bags
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	Plastic bag 50 lb, Bulk box/bag	☑ On label

6. Manner in Which Label is Affixed to Product: ☑ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
Larry Antilla	Staff Director	(602)438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
[signature]	Staff Director	Larry Antilla	3/22/04

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Aspergillus flavus AF36

FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS <------ SUNRET

For displacing aflatoxin producing fungi

Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, ***Aspergillus flavus*** AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: *Aspergillus flavus* strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

* Contains a minimum of 3,000 CFU/gram in the End Use Product

ACCEPTED
JUN 24 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71693-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

For other pesticide handlers under the scope of Worker Protection Standard:
Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

User Safety Recommendations:
User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

NON FEE ITEM

DIVISION: Biopesticides and Pollution Prevention

BRANCH: MPB

EPA FILE SYMBOL/REG. NO: 71693-1

PIN PUNCH/START DATE: 3-26-04

BPPD DATE: 3-29-04

PR 86-5 PASS DATE: N/A

ACTION CODE: 300

RAL: S. Bacchus

REMARKS: (IR-4)
Label amdt to add. California
to label.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 13, 2005

Michael Braverman, Ph.D.
Interregional Research Project No. 4
IR-4 Project Coordinator
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Braverman:

Extension Request dated December 08, 2005
***Aspergillus flavus* AF36 - EPA Registration No. 71693-1**
Conditions of Registration

The Agency has reviewed your request of December 08, 2005 to extend the deadline for submitting the reports related to fulfilling the conditions of registration for *Aspergillus flavus* AF36 - EPA Registration No. 71693-1, which are due on December 24, 2005. Your request for extra time to compile the reports is accepted, and the deadline is extended to June 24, 2006.

The existing conditional registration for product number 71693-1 will continue until the submitted reports are evaluated. If the reports satisfy the specified conditions, the product will be eligible for an unconditional registration.

Should you have any additional questions regarding this matter, please contact Shanaz Bacchus at 703-308-8097. You may also contact Mr. Dennis Szuhay at 703-305-6098, when Ms. Bacchus is out of the office on annual leave between December 15, 2005 and January 06, 2006.

Sincerely,

Janet Andersen, Ph.D.
Director
Biopesticides and Pollution Prevention Division

The IR-4 Project

Providing Safe and Effective Pest Management Solutions for Specialty Crop Growers

IR-4 Headquarters
Center for Specialty Crop Pest Management
Rutgers, The State University of New Jersey
681 US #1 South
North Brunswick, NJ 08902-3390
732.932.9575 fax: 732.932.8481
www.ir4.rutgers.edu

Ms. Shanaz Bacchus
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
Crystal Mall 2, Room 910
1801 South Bell Street
Arlington, VA 22202
(703)308-8097

December 8, 2005

RE: AF36 Conditional Registration – Time extension request until June 24, 2006.
IR-4 PR# 52B

Dear Ms Bacchus:

The purpose of this letter is to request a time extension to meet the conditional registration requirements for Aspergillus flavus AF36 (EPA Registration Number 71693-1) in cotton. The IR-4 Project is submitting this request on behalf of the Arizona Cotton Research and Protection Council. AF36 was conditionally approved on June 24, 2003(Attached).. The 30 month period which was requested to submit the additional information would be December 24, 2005. We are hereby requesting an extension until June 24, 2006. From my communication with the registrant and Dr Peter Cotty, the data have been collected but have not been put into a report. I also need time to take their report and format it for EPA submission. Thank you for your consideration.

Please let me know if you have any questions or anything else needs attention.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Sincerely

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481

CC by e-mail: Peter Cotty, Larry Antilla

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W. (7511C)
Washington, D.C. 20460

EPA Reg. Number: 71693-1

Date of Issuance: JUN 24 2003

NOTICE OF PESTICIDE:
__X__ Registration
_____ Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product: *Aspergillus flavus* AF36

Name and Address of Registrant (include ZIP Code):

Mr. Larry Antilla
Arizona Cotton Research and Protection Council
3721 East Wier Avenue
Phoenix, Arizona 85040-2933

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you do the following:

1. Change the label by revising the EPA Registration Number to read, "EPA Reg. No. 71693-1".

2. Submit five copies of the revised final printed label for the record.

3. The following data are required within 30 months of the conditional registration date:
   (a) analyses of 5 production batches to include:
   (i) certifications of limits;
   (ii) identification of *A. flavus* AF36 by either DNA analysis or some other method different from the vegetative compatibility method now in use;
   (iii) analysis and quantification of metabolites and other unintentional ingredients, including aflatoxin analysis by High Pressure Liquid Chromatography (HPLC) or Gas Chromatography (GC);
   (iv) identification and enumeration of potential human pathogens;
   (v) storage stability; and
   (vi) viability data.
   (b) efficacy data from large scale trials in Texas.

All batches containing human pathogen, metabolites and unintentional ingredients above regulatory levels must be destroyed.

Signature of Approving Official: See next page

Date: 6/24/03

EPA Form 8570-6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 28 2004

Mr. Larry Antilla
Arizona Cotton and Research and Protection Council
3721 East Wier Avenue
Phoenix, AZ 85040-2933

Subject:

Label Amendment - Use of *Aspergillus Flavus* AF36 on Cotton in Certain Counties in the State of California
EPA Registration No. 71693-1
Label Amendment Application Dated 4/15/04

Dear Mr. Antilla:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(C), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

This pesticide is for use on cotton in the desert regions of Southern California as specified on the label. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the draft label is enclosed for your records.

If you have any questions regarding this matter, do not hesitate to email Chris Pfeifer at pfeifer.chris@epa.gov or call him at 703-308-0031.

Sincerely,

Dennis Szuhay, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

Enclosure
CJP:092804:716931:006456

CONCURRENCES								
SYMBOL	CJP							
SURNAME	PFEIFER							
DATE	9/28/04							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

*U.S. Government Printing Office: 2001 — 715-264/56169

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 2 8 2004

Mr. Larry Antilla
Arizona Cotton and Research and Protection Council
3721 East Wier Avenue
Phoenix, AZ 85040-2933

Subject:

Label Amendment - Use of *Aspergillus Flavus* AF36 on Cotton in Certain Counties in the State of California
EPA Registration No. 71693-1
Label Amendment Application Dated 4/15/04

Dear Mr. Antilla:

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1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

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A stamped copy of the draft label is enclosed for your records.

If you have any questions regarding this matter, do not hesitate to email Chris Pfeifer at pfeifer.chris@epa.gov or call him at 703-308-0031.

Sincerely,

Dennis Szuhay, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

Enclosure

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W. (7511C)
Washington, D.C. 20460

EPA Reg. Number: 71693-1

Date of Issuance: JUN 24 2003

Term of Issuance: Conditional

Name of Pesticide Product: *Aspergillus flavus* AF36

NOTICE OF PESTICIDE:

__X__ Registration

____ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Mr. Larry Antilla
Arizona Cotton Research and Protection Council
3721 East Wier Avenue
Phoenix, Arizona 85040-2933

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you do the following:

1. Change the label by revising the EPA Registration Number to read, "EPA Reg. No. 71693-1".

2. Submit five copies of the revised final printed label for the record.

3. The following data are required within 30 months of the conditional registration date:
   (a) analyses of 5 production batches to include:
   (i) certifications of limits;
   (ii) identification of *A. flavus* AF36 by either DNA analysis or some other method different from the vegetative compatibility method now in use;
   (iii) analysis and quantification of metabolites and other unintentional ingredients, including aflatoxin analysis by High Pressure Liquid Chromatography (HPLC) or Gas Chromatography (GC);
   (iv) identification and enumeration of potential human pathogens;
   (v) storage stability; and
   (vi) viability data.
   (b) efficacy data from large scale trials in Texas.

All batches containing human pathogen, metabolites and unintentional ingredients above regulatory levels must be destroyed.

SB:7511C:06232003:006456:71693 t

Signature of Approving Official: See next PAGE

Date: 6/24/03

EPA Form 8477LR

CONCURRENCES

SYMBOL	7511C							
SURNAME	Pacchioli							
DATE	6/23/03							

OFFICIAL FILE COPY

Any requests for time extensions to provide the data listed above must be submitted in writing prior to the appropriate deadline. If EPA determines, at any time, that additional data are required to maintain in effect an existing conditional registration, the Agency will require submission of such data under Section 3(c)2(B) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the approved label in connection with this conditional registration is enclosed for your records. If you have any other questions regarding this registration, do not hesitate to email Shanaz Bacchus at *bacchus.shanaz@epa.gov* or call her on 703-308-8097.

Sincerely,

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution Prevention Division

cc: file 71693-R
Encl.

Michael Braverman
<braverman@AESOP.Rutgers.edu>
07/14/04 02:55 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Peter Colty <pjcolty@srrc.ars.usda.gov>, Larry Antilla <LAntilla@AZcolton.com>, Phil Wakelyn <pwakelyn@cotton.org>
Subject: FW: CA counties needing AF36/cotton

Shanaz

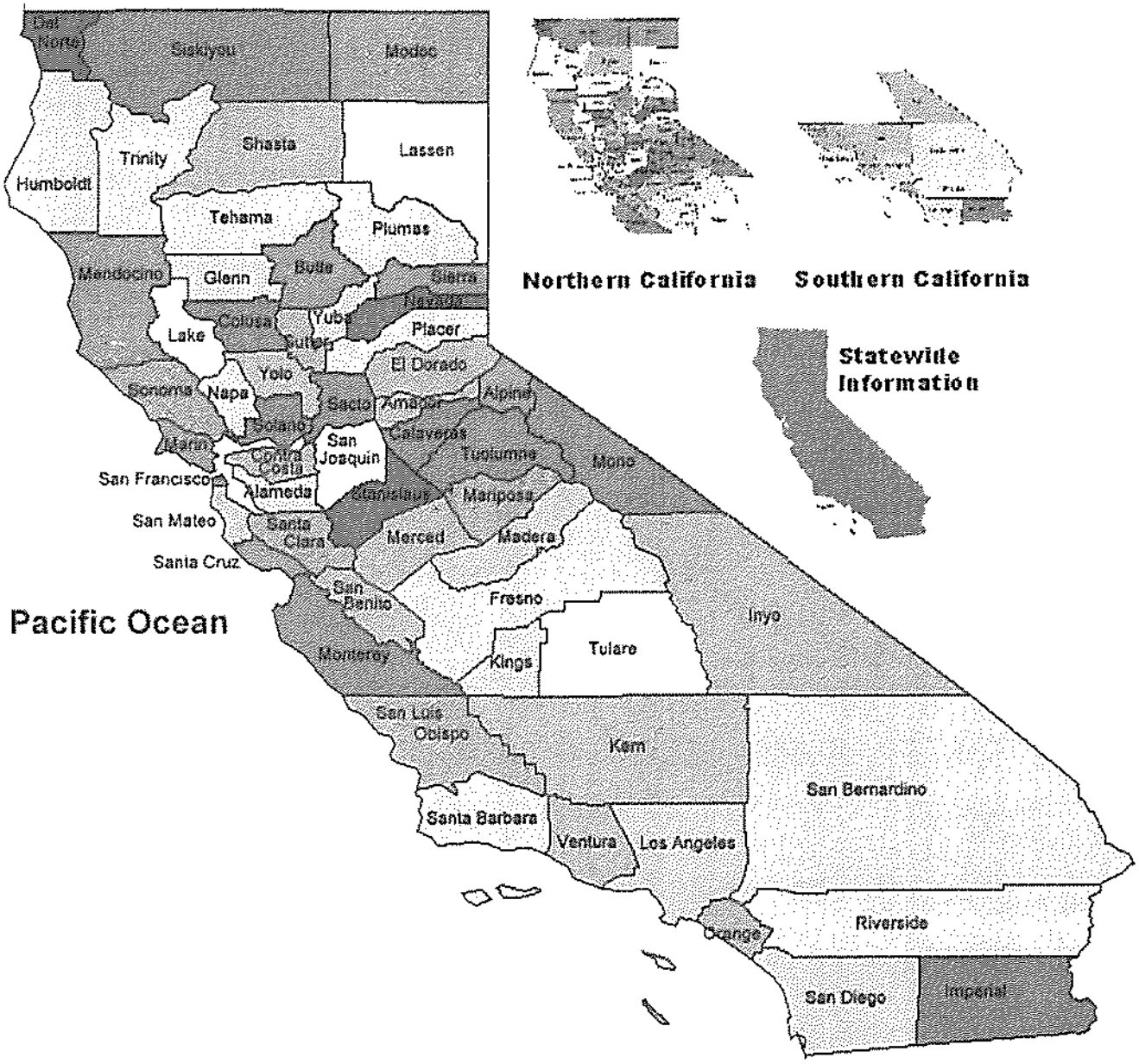
I spoke to Peter. The counties AF36 are likely to be used-needed in for cotton are Imperial, Riverside and San Bernadino. A map of California counties is below. These 3 counties are in the southern part of California adjoining Arizona. Per county cotton production information is also listed below. Please let me know if you need hard copies of this.

Thanks

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
http://ir4.rutgers.edu/

BIOPESTICIDES

MICROBIALS PHEROMONES NATURAL PRODUCTS



CALIFORNIA COTTON, UPLAND: Acreage, Yield And Production By County, 2003 Preliminary

County	Planted	Harvested	Yield/Acre	Production	
		Acres		*Pounds*	*Bales*
Del Norte	---	---	---	---	

Note to File

Subject: Rationale for Limiting Pesticide Use to Specific Counties in California
Date: 9/28/4
To: File
From: Chris Pfeifer

An application for amendment was originally submitted by the registrant to add California to the list of states approved for the use of *Aspergillus flavus* (AF 36) on cotton. After several telephone conversations and email correspondences between Michael Braverman, Peter Cotty, Chris Pfeifer and Shanaz Bacchus, it became apparent that the addition of the whole state of California was not appropriate to the label at this time. The registrant only intended to experiment with the use of the product in cotton growing counties that were contiguous to the Arizona cotton growing sites. It was pointed out that these contiguous California counties were all part of the Lower Colorado Valley Subregion, and that all the counties shared an ecosystem, which is marked by the same microclimate and vulnerability to aflatoxin contamination. Therefore, rather than extending approval of the use of the product beyond the shared environment in which it is already applied, the Agency thought it prudent to further condition the amendment to the specific and contiguous counties in California.

Nonetheless, the applicants have a reasonable case for eventually extending the use of the product to other parts of the state. The registrant's rationale is that the product is only efficacious and practical in cotton growing areas that share the same characteristics as those of the Lower Colorado Valley Subregion - that is - areas that are hot and arid, and where crops require irrigation. And regardless of their exact location, these desert-like areas are typically marked by similar microflora and microfauna, and are the only places where afatoxin producing microbes are truly problematic. As such, it is posited that the use of the product in more like areas would not create any exposure situations or risks beyond those which are already known. The registrant indicated that they would submit a written rationale for adding the whole state at a later date, should they feel that there is a real need for the product beyond the specific counties where there is both present need and interest. However, for the time being, the registrant is content to limit the product to the specific counties mentioned on the label.

ROUTING & TRANSMITTAL SLIP — September 28, 2004

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Dennis Szuhay	DS	9-28
2. Chris Pfeifer	CP	9/28/4
3. Shanaz Bacchus		
4.		
5.		

	Action		File		Note And Return
x	Approval	x	For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	x	Signature
	Coordination		Justify	x	Initials/Concurrence

REMARKS

Subject:
Arizona Cotton and Research Protection Council
EPA Registration No. 71693-1
Label Amendment to Use AF 36 on Cotton in Certain Counties in California
Application Dated 4/15/4

Enclosed are:
1) 3 copies of the Amendment Letter (2 for concurrence)
2) The label
3) Correspondence with rationale for selection of counties.

FROM (Name, org. symbol, Agency/Post)	Room No.-Bldg.
Chris Pfeifer EPA BPPD	911GG Phone No. 703-308-0031

Aspergillus flavus AF36

FOR USE ONLY IN THE STATES OF ARIZONA , TEXAS
AND CALIFORNIA(Imperial, Riverside and San Bernadino counties only)

For displacing aflatoxin producing fungi

Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, ***Aspergillus flavus*** AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: *Aspergillus flavus* strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

* Contains a minimum of 3,000 CFU/gram in the End Use Product

ACCEPTED
9/24/14
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71693-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

For other pesticide handlers under the scope of Worker Protection Standard:
Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

User Safety Recommendations:
User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

Re-Entry Statement:
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to cotton to displace aflatoxin-producing strains of *Aspergillus flavus*.

Aspergillus flavus AF36 is a living fungus growing on sterile wheat seed, which serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur at irrigation), *Aspergillus flavus* AF36 will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi are spread.

Ground Application:

1. Apply ***Aspergillus flavus*** **AF36** with a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of ***Aspergillus flavus*** **AF36** under the canopy and to minimize delivery of ***Aspergillus flavus*** **AF36** to furrows.
3. ***Aspergillus flavus*** **AF36** has been shown to be effective when applied in late May or early June, prior to first bloom. Make a single application during the last cultivation before bloom.
4. Furrow irrigating the crop with at least 2 inches of water within three days after application of ***Aspergillus flavus*** AF36 will provide the best results.
5. Use 10 lbs of ***Aspergillus flavus*** **AF36** per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Apply by air at the same rate as for ground application. Cultivation after application may diminish efficacy.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.
PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.
CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

Aspergillus flavus AF36

FOR USE ONLY IN THE STATES OF ARIZONA , TEXAS
AND CALIFORNIA(Imperial, Riverside and San Bernadino counties only)

For displacing aflatoxin producing fungi

Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, ***Aspergillus flavus*** AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: *Aspergillus flavus* strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized).....	99.9992%
Total:	100%

* Contains a minimum of 3,000 CFU/gram in the End Use Product

ACCEPTED
7/26/4
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71693-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

For other pesticide handlers under the scope of Worker Protection Standard:
Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

User Safety Recommendations:
User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

Re-Entry Statement:
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

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WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

Michael Braverman
<braverman@AESOP.Rutgers.edu>

07/14/04 03:14 PM

To: Chris Pfeifer/DC/USEPA/US@EPA, jinouye@cdpr.ca.gov
cc: Shanaz Bacchus/DC/USEPA/US@EPA
Subject: FW: CA counties needing AF36/cotton

Chris and John

Sorry I didn't copy you on this.

Shanaz our e-mails crossed.....

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
http://ir4.rutgers.edu/

BIOPESTICIDES


MICROBIALS


PHEROMONES


NATURAL PRODUCTS

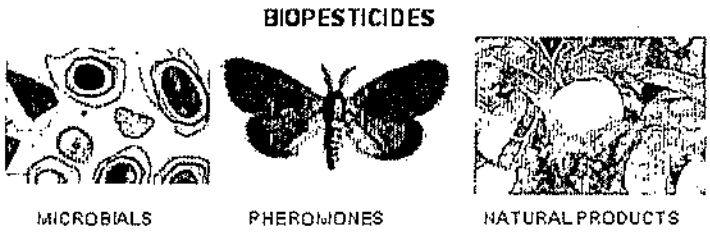
-----Original Message-----
From: Michael Braverman [mailto:braverman@aesop.rutgers.edu]
Sent: Wednesday, July 14, 2004 1:55 PM
To: Shanaz Bacchus (Bacchus.Shanaz@epamail.epa.gov)
Cc: Peter Cotty; Larry Antilla (LAntilla@AZcotton.com); Phil Wakelyn (pwakelyn@cotton.org)
Subject: FW: CA counties needing AF36/cotton

Shanaz

I spoke to Peter. The counties AF36 are likely to be used-needed in for cotton are Imperial, Riverside and San Bernadino. A map of California counties is below. These 3 counties are in the southern part of California adjoining Arizona. Per county cotton production information is also listed below. Please let me know if you need hard copies of this.

Thanks

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
http://ir4.rutgers.edu/



CALIFORNIA COTTON, UPLAND: Acreage, Yield And Production By

County, 2003 Preliminary

County	Planted	Harvested	Yield/Acre	Production	Bales
	Acres			*Pounds*	
Del Norte	---	---	---	---	
Humboldt	---	---	---	---	
Mendocino	---	---	---	---	
District 10 Total	---	---	---	---	
Shasta	---	---	---	---	
Siskiyou	---	---	---	---	
Trinity	---	---	---	---	
District 20 Total	---	---	---	---	
Lassen	---	---	---	---	
Modoc	---	---	---	---	
Plumas	---	---	---	---	
District 30 Total	---	---	---	---	
Alameda	---	---	---	---	
Contra Costa	---	---	---	---	
Lake	---	---	---	---	
Marin	---	---	---	---	
Monterey	---	---	---	---	
Napa	---	---	---	---	
San Benito	---	---	---	---	
San Francisco	---	---	---	---	
San Luis Obispo	---	---	---	---	
San Mateo	---	---	---	---	
Santa Clara	---	---	---	---	
Santa Cruz	---	---	---	---	
Sonoma	---	---	---	---	
District 40 Total	---	---	---	---	
Butte	---	---	---	---	
Colusa	4,700	4,400	1,364	12,500	
Glenn	2,100	1,800	1,067	4,000	
Sacramento	---	---	---	---	
Solano	---	---	---	---	

Sutter	1,500	1,400	1,063	3,100
Tehama	---	---	---	---
Yolo	---	---	---	---
Yuba	---	---	---	---
Other Counties 1/	100	100	960	200
District 50 Total	**8,400**	**7,700**	**1,234**	**19,800**
Fresno	188,000	187,000	1,325	516,100
Kern	91,400	91,000	1,333	252,800
Kings	94,100	93,400	1,295	252,000
Madera	18,500	18,000	1,200	45,000
Merced	70,400	70,000	1,247	181,900
San Joaquin	---	---	---	---
Stanislaus	---	---	---	---
Tulare	58,500	57,600	1,346	161,500
Other Counties 1/	200	200	960	400
District 51 Total	**521,100**	**517,200**	**1,308**	**1,409,700**
Alpine	---	---	---	---
Amador	---	---	---	---
Calaveras	---	---	---	---
El Dorado	---	---	---	---
Inyo	---	---	---	---
Mariposa	---	---	---	---
Mono	---	---	---	---
Nevada	---	---	---	---
Placer	---	---	---	---
Sierra	---	---	---	---
Tuolumne	---	---	---	---
District 60 Total	---	---	---	---
Imperial	6,100	5,900	1,554	19,100
Los Angeles	---	---	---	---
Orange	---	---	---	---
Riverside	13,500	13,400	1,587	44,300
San Bernardino	900	800	1,260	2,100
San Diego	---	---	---	---
Santa Barbara	---	---	---	---

Ventura	---	---	---	---
District 80 Total	**20,500**	**20,100**	**1,564**	**65,500**
STATE	**550,000**	**545,000**	**1,317**	**1,495,000**

1/ Includes one or more counties within a district that normally have less than 500 acres planted.

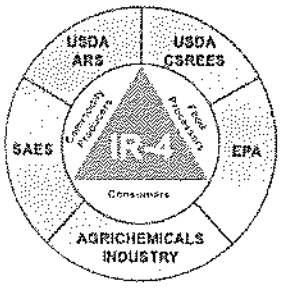
Return to: [Table of Contents for County Estimates] [CASS Publications] [CASS Homepage] [Questions?]

California Agricultural Statistics Service
P.O. Box 1258
Sacramento, CA 95812
Phone: (916) 498-5161
Fax: (916) 498-5186
E-mail: nass-ca@nass.usda.gov

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-848 t
http://ir4.rutgers.edu/

BIOPESTICIDES

MICROBIALS PHEROMONES NATURAL PRODUCTS



Interregional Research Project No. 4
Center for Minor Crop Pest Management

Ms. Shanaz Bacchus
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
Crystal Mall 2, Room 910
1921 Jefferson Davis Highway
Arlington, VA 22202
(703)308-8097

March 24, 2004

RE: AF36 LABEL AMENDMENT- Addition of the State of California.

Dear Ms Bacchus:

The purpose of this letter is to request a label amendment for Aspergillus flavus AF36 (EPA Registration Number 71693-1) in cotton. The IR-4 Project is submitting this request on behalf of the Arizona Cotton Research and Protection Council. The IR-4 Project authorizes the Environmental Protection Agency to reference and share any an all waivers, data, reviews and other documents utilized in review of this label amendment with the California Department of Pesticide Regulation. The only change is the addition of the state of California to the label. There are no other changes in the active ingredients, inerts or any other aspect of the product or the label.

The following is a list of the enclosures:

1. Form 8570-1

2. EPA stamped label for AF36 with the current states of Arizona and Texas highlighted.

3. Amended label with the State of California added and highlighted

4. Five additional copies of the amended label.

5. Bridging discussion- Relevance of Materials used for the Registration of Aspergillus flavus AF36(EPA Reg. No. 71693-1) to the Registration for Uses in California. --Written by Peter Cotty, USDA/ARS.

6. Letter of Authorization- Mr Larry Antilla, Arizona Cotton Research and Protection Council

7. Letter of Authorization- Dr Peter Cotty, USDA/ARS

Please let me know if you have any questions or anything else needs attention.

Sincerely

Michael Braverman

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481

CC by e-mail: Phil Hutton, Dennis Szuhay, John Inouye, Peter Cotty, Larry Antilla, Phil Wakelyn.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
AZ Cotton Research and Protection Council 71693-1.	Shanaz Bacchus	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Asperoillus flavus AF36		

5. Name and Address of Applicant *(Include ZIP Code)*

Arizona Cotton Research and Protection Council
3721 E. Weir Avenue
Phoenix, Arizona 85040-2933

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
This is a label amendment to add California to the label

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [ ] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [x] Other (Specify) Bulk boxes, bags
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	Plastic bag 50 lb, Bulk box/bag	[x] On label

6. Manner in Which Label is Affixed to Product: [x] Lithograph Paper glued Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Larry Antilla	Staff Director	(602)438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
[signature]	Staff Director	
4. Typed Name	**5. Date**	
Larry Antilla	3/22/04	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 20 2003

MEMORANDUM

SUBJECT: Consideration of a conditional registration of the active ingredient *Aspergillus flavus* AF36 (PC Code 006456, EPA Registration Number 71693-R) for use on cotton in Arizona and Texas, and an exemption from tolerance for cotton and its food/feed commodities associated with the use of this active ingredient (Pesticide Petition 8E5001).

---------- DECISION MEMORANDUM ----------

FROM: Janet L. Andersen, Director
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs

TO: James Jones, Director
Office of Pesticide Programs

ISSUE

Should the Agency grant a conditional registration under FIFRA § 3(c)(7)(C) for the new microbial active ingredient, *Aspergillus flavus* strain AF36 (PC Code 006456, EPA Registration Number 71693-R) as an antifungal pesticide to reduce aflatoxin-producing colonies of *A. flavus* on cotton in Arizona and Texas?

Also, should the Agency grant an exemption from tolerance for residues of the active ingredient, *Aspergillus flavus* strain AF36, on cotton and its food/feed commodities as requested in Pesticide Petition 8E5001?

APPLICANT INFORMATION

The application for the use of this new active ingredient, *Aspergillus flavus* AF36, and the Pesticide Petition 8E5001 were filed by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390, on behalf of Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, Arizona 85040-2933.

BACKGROUND AND CONCLUSIONS

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed available and submitted data and information regarding the proposed use of *Aspergillus flavus* AF36, a non-aflatoxin-producing (atoxigenic) strain of *A. flavus*. Evaluations of the data and conclusions are summarized and discussed in the attached Biopesticide Registration Action Document (BRAD). *Aspergillus flavus* AF36 (also called AF36) is to be applied at less than 0.01 lb of the active ingredient per acre. The applicant proposes a single, seasonal, prebloom application to cotton fields in Arizona and Texas. AF36 apparently displaces aflatoxin-producing strains of *A. flavus* from cotton fields and cotton, with a potential concomitant reduction of aflatoxin, a public health hazard. There is no other pesticide registered for the reduction of aflatoxin-producing colonies of *A. flavus*. For these reasons, *Aspergillus flavus* AF36 qualifies for an automatic presumptive finding for a conditional registration, and its use is presumed to be in the public interest. Sufficient data are available to support granting a conditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

While there are data gaps, the available and submitted data, which have been reviewed, comply with the Food Quality Protection Act of 1996. The health effects database support an exemption from tolerance for residues of *Aspergillus flavus* strain AF36 in/on cotton and its food/feed commodities. No toxicity endpoints were identified to justify setting a numerical tolerance for *A. flavus* AF36. Cotton itself is not a dietary commodity and residues of AF36 are not likely to survive the processing of cottonseed into its oil or meal. Thus, secondary transfer of AF36 to meat and milk are not likely to occur. Even if there was any potential aflatoxin associated with the use of AF36, in/on cotton food/feed commodities, those levels must meet the aflatoxin standards regulated by the Food and Drug Administration. Dietary, non-occupational dermal and inhalation exposures, as well as cumulative and aggregate exposures and risks are not likely to be greater than those which currently exist to the naturally occurring *A. flavus* strains. Thus, minimal to non-existent risks via dietary or non-occupational dermal and inhalation exposures are expected.

The applicant requested that data be waived for acute dermal toxicity/pathogenicity, primary dermal irritation, primary eye irritation, intraperitoneal and immune response studies. BPPD accepted the rationales submitted by the applicant to waive these data requirements. The justifications included (a) the non-toxic, non-infective acute oral and pulmonary effects, (b) a low application rate, (c) minimal to no pesticide drift based on the granular nature of the pesticide, (d) the ubiquitous occurrence of *Aspergillus* fungi, and (e) exposures which are not likely to be above background levels.

BPPD has not identified any acute, subchronic, chronic, immune, endocrine or dietary exposure issues that might affect human adults, infants and children. Because there are no threshold effects of concern to human adults, infants and children, when AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. Thus, there is a reasonable certainty of no incremental adverse effects to human adults, infants and children, and to the environment from the use of this active ingredient. Potential occupational exposure is mitigated by use of appropriate Personal Protective Equipment as required by the Worker Protection Standards.

Submitted data indicate no potential incremental adverse effects to avian and honey bee

Relevance of Materials used for the Registration of *Aspergillus flavus* AF36 (EPA Reg. No. 71693-1) to Registration for Uses in California

Peter J. Cotty
Research Plant Pathologist
Agricultural Research Service, U.S. Department of Agriculture
Division of Plant Pathology & Microbiology, Dept. of Plant Sciences
University of Arizona, Tucson, Arizona

In 2003 *Aspergillus flavus* AF36 was granted a section 3 registration for use in Arizona and Texas. Since that time, farmers in aflatoxin high-risk areas in California have expressed interest in utilizing this biopesticide in aflatoxin management programs. Based on current production practices, the maximum acreage to be treated would be 30,000 acres. This includes cotton in the Imperial Valley, the Palo Verde Valley, the Winterhaven area (adjacent to Yuma), and the Needles area across from the Mohave Valley of Arizona. Because these California production areas have more in common with the Yuma County, Arizona production areas than with cotton production area in the remainder of California, the efficacy data and other data generated in Yuma County should be considered relevant and equivalent to data that would be generated in these areas of California. These California areas differ from other cotton production areas of California in that they experience severe aflatoxin contamination similar to that experienced in the lower elevation Arizona production areas. The most prominent factors leading to crop vulnerability in both the Arizona and California production areas are highly toxigenic fungi, high temperatures, and exposure of mature bolls to humidity either through irrigation after initial boll opening or through late season rain evens.

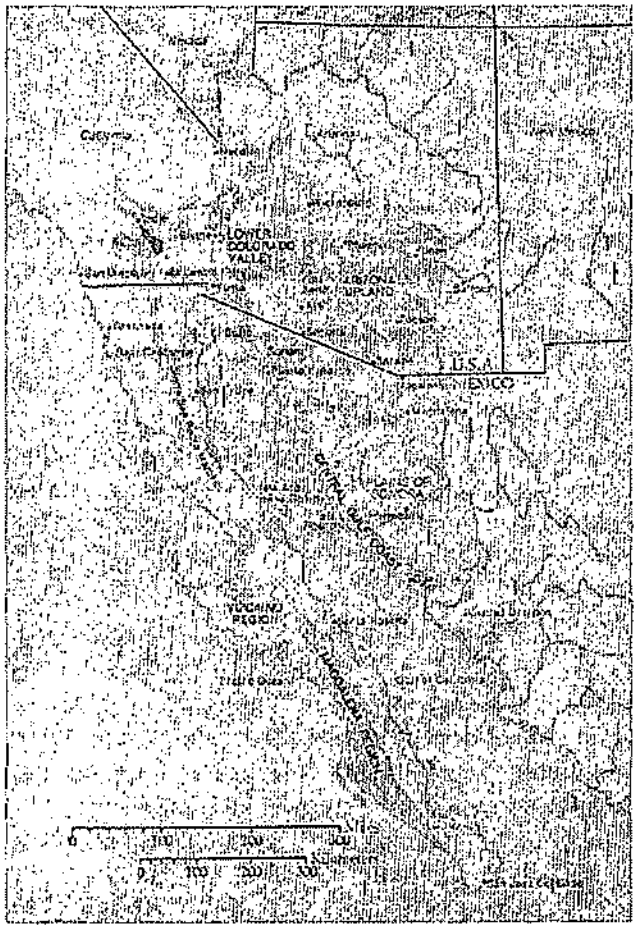
The Yuma Valley is at the center of the Lower Colorado Valley Subregion of the Sonoran Desert Region. Climatic conditions throughout the Lower Colorado Valley is described below. In this region, cotton production occurs primarily in several valleys and nearby mesas. The major production areas are the Yuma Valley, Mohawk Valley, Parker Valley, Mohave Valley, Hyder and Paloma areas of Arizona and the Imperial Valley and Palo Verde Valley of California. These areas share similar crop rotations, agronomic practices, climates, and soil salinity concerns. The water used to irrigate the Imperial Valley actually flows through the All American Canal from Yuma and same Colorado River water irrigates all these areas. The use pattern of Aspergillus flavus AF36 will be the same in California and Arizona. Sterilized wheat seed colonized with AF36 will be applied to the soil surface and be dependent on irrigation for sufficient moisture to allow the fungus to grow. AF36 will sporulate on the wheat and compete with aflatoxin producers during competition for crop associated resources and during crop colonization.

Most of the efficacy and ecological data for the section 3 registration granted by EPA for *Aspergillus flavus* AF36 was developed in Yuma County Arizona and

should therefor be considered during the registration process for California. Indeed, the fungus *Aspergillus flavus* Af36 was initially isolated from cottonseed produced in the Yuma Valley of Arizona. The Yuma Valley is on the boarder with California and is within 65 miles of the majority of acreage that might be treated in California. If the small acreage near Needles is considered then all acreage of potential interest occurs within 135 miles of Yuma. These distances are relatively small when one considers the vast areas of Arizona and South Texas covered by the current registration.

Aspergillus flavus AF36 is known to occur in several counties of California and on cotton in the Imperial Valley. Nine cottonseed samples from the 2003 Imperial Valley crop were provided by Robert Bedwell, manager, Planters Ginning Co. in Brawley, CA. Planters is the last remaining cotton gin in the Imperial Valley. *Aspergillus flavus* occurred at high concentrations on the cottonseed ranging from 129 propagules (probably spores) of *A. flavus* per gram of cottonseed to 2,449 propagules/g and averaging 812 propagules per gram. Six of the nine cottonseed samples had detectable quantities of *Aspergillus flavus* AF36 ranging from 6% of the *A. flavus* present on the seed to 30% of the *A. flavus* on the seed and making up an average of 10.9% of the *A. flavus* on the cottonseed crop from the Imperial Valley. The cottonseed from the Imperial Valley had an average of 63.7 propagules of *Aspergillus flavus* AF36 per gram of seed. These results suggest AF36 is a common natural constituent of the mycoflora on the cotton crop of the Imperial Valley. Since soil is the source AF36 inoculum, its presence in Imperial Valley cotton demonstrate that AF36 is already in California soils. In addition it would be present in any cotton tissue left in the field. Therefore this does not represent an introduction of a new organism, but a temporary shift in the population in favor of the atoxigenic strain, AF36. AF36 has also been isolated in California pistachio and fig orchards (see abstract below). Therefore man and the environment are already exposed to AF36 due to its natural occurrence in California.

Lower Colorado River Valley. Named for its location surrounding the lower Colorado River in parts of four states, this is the largest, hottest, and driest subdivision of the Sonoran Desert. It challenges the Mohave Desert's Death Valley as the hottest and driest place in North America. Summer highs may exceed 120 F (48.5 C), with surface temperatures approaching 180 (82 C). The intense solar radiation from cloudless skies and low humidity (often less than 10%) suck the life-sustaining water from exposed plants, water that cannot be replaced from the parched mineral soil.



Annual rainfall in the driest sites averages less than three inches (75 mm), and some localities have gone nearly three years with no rain. Even so, life exists here, abundantly in the rare wet years.

The geography is mostly broad, flat valleys with widely-scattered, small mountain ranges of mostly barren rock. There is also a sand sea (the Gran Desierto) and the spectacular Pinacate volcanic field. The valleys are dominated by low shrubs, primarily creosote bush (Larrea divaricata) and white bursage (Ambrosia dumosa). These are the two most drought- tolerant plants in North America, but in driest areas of this subdivision even they are restricted to drainage courses (i.e., they become riparian plants!). Trees are found only in the larger washes. The mountains support a wider variety of shrubs and cacti, but the density is very sparse. Columnar cacti, one of the indicators of the Sonoran Desert, are rare (virtually absent in California) and restricted to drainages. Annual species comprise well over half the flora (90% at the driest sites); they are mostly winter-growing species and appear in numbers only in wet years.

This is the only part of the Sonoran Desert that extends into California, where it is usually called the Colorado Desert. North of a sagging line between Palm

Springs and Needles, California, it merges almost imperceptibly with the lower Mohave Desert. From: http://www.desertmuseum.org/desert/sonora.html.

The below abstract has been submitted for a poster to be presented at the Annual Meeting of the American Phytopathological Society in Anaheim CA in August, 2004.

Incidence of the atoxigenic Aspergillus flavus strain AF36 in pistachio and fig orchards in California. M.A. DOSTER (1), T.J. Michailides (1), and P.J. Cotty (2). (1) Dept. Plant Pathology, University of California, Davis/Kearney Agricultural Center, Parlier, CA 93648; (2) USDA-ARS/University of Arizona, Tucson, AZ 85721.

Aflatoxin, produced by the fungi Aspergillus flavus and A. parasiticus, can contaminate many crops including almonds, figs, pistachios, and walnuts in California. Certain strains of A. flavus are unable to produce aflatoxins. One such atoxigenic strain, AF36, has been used successfully as a biocontrol agent to substantially reduce aflatoxin contamination in commercial cotton fields in Arizona and Texas. The objective of the current study was to determine the natural occurrence of AF36 and other atoxigenic strains in commercial orchards in California using vegetative compatibility analyses. Out of 431 A. flavus isolates from commercial pistachio orchards, 6.3%, 2.1%, and 1.6% belonged to atoxigenic strains AF36, A564, and A815, respectively. In addition, out of 97 isolates from fig orchards, 6.2%, 1.0%, and 1.0% belonged to strains AF36, A564, and A815, respectively. So far, AF36 has been detected in commercial pistachio orchards in five counties, which contain approximately 89% of the bearing acreage in California. In conclusion, the atoxigenic strain AF36 occurs naturally in pistachio and fig commercial orchards in California and is widespread throughout the major pistachio growing areas.

A C R P C
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 E WIER AVE
PHOENIX AZ 85040-2933
602-438-0059 (PH)
602-438-0407 (FAX)

Ms. Shanaz Bacchus
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
Crystal Mall 2, Room 910
1921 Jefferson Davis Highway
Arlington, VA 22202

March 15, 2004

Dear Ms Bacchus:

The purpose of this correspondence is to authorize the U.S. Environmental Protection Agency to share its data and reviews of *Aspergillus flavus* AF36 with the California Department of Pesticide Regulation.

If you need additional information please notify me.

Sincerely,

Larry Antilla
Director

CC: Michael Braverman, John Inouye

USDA

United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

March 17, 2004

Ms. Shanaz Bacchus
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
Crystal Mall 2, Room 910
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Arlington, VA 22202

Dear Ms Bacchus:

The purpose of this correspondence is to authorize the U.S. Environmental Protection Agency to share its data and reviews of *Aspergillus flavus* AF36 with the California Department of Pesticide Regulation.

If you need additional information please notify me through Dr. Michael Braverman of the IR-4.

Sincerely,

Peter J. Cotty
Research Plant Pathologist

CC: Michael Braverman, John Inouye

ars

Agricultural Research Service
Division of Plant Pathology and Microbiology, University of Arizona
Room 240 Forbes Building, 1140 East South Campus Drive, Tucson, Arizona 85721
Voice: 520.626.5049 Fax: 520.621.9290
e-mail: pjcotty@srrc.ars.usda.gov

(Federal Register: July 14, 2003 (Volume 68, Number 134)]
[Rules and Regulations]
[Page 41535-41541]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr14jy03-8]

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
[OPP-2003-0138; FRL-7311-6)

Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial antifungal agent Aspergillus flavus AF36, a non-aflatoxin-producing member of the naturally-occurring genus of fungi Aspergillus, in or on the food/feed commodity cotton, when the pesticide is used according to its label instructions as a prebloom application. The Interregional Research Project Number 4 [IR-4), on behalf of the Arizona Cotton Research and Protection Council, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Aspergillus flavus AF36 in or on cotton and its food/feed commodities.

DATES: This regulation is effective July 14, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0138, must be received on or before September 12, 2003.

ADDRESSES: Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: <A HREF="mailto:bacchus.shanaz@epa.gov">bacchus.shanaz@epa.gov</A>.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production [NAICS code 112]
- Food manufacturing (NAICS code 311)

• Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0138. The official public docket is intended to serve as a repository for materials (i.e.,documents and other information) submitted to the Agency in connection with this action and/or relied upon by the Agency in

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taking this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. To the extent that a particular document is not located in the official public docket, consult the person listed under FOR FURTHER INFORMATION CONTACT.

The legacy docket for this case is OPP-2003-0020, which was set up in connection with the Notice of Filing of this pesticide petition, 8E5001. It contains the Federal Register Notice dated February 14, 2003, (68 FR 7554), which was published to announce this petition, other relevant Federal Register documents associated with the exemption from temporary tolerance which preceded this permanent exemption from tolerance, and comments received in response to the publication of this petition.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the ``Federal Register'' listings at <A HREF="http://www.epa.gov/fedrgstr/">http://www.epa.gov/fedrgstr/</A>. A frequently updated electronic version of 40 CFR part 180 is available at <A HREF="http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html">http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html</A>, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <A HREF="http://www.epa.gov/opptsfrs/home/guidelin.htm">http://www.epa.gov/opptsfrs/home/guidelin.htm</A>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <A HREF="http://www.epa.gov/edocket/">http://www.epa.gov/edocket/</A> to submit

neither toxic nor infective following oral administration of a single dose. The acute oral test resulted in a Toxicity Category IV classification with a lethal dose (LD)₅₀ greater than 5,000 milligrams/kilogram (mg/kg) body weight [MRID 43972403; BPPD Data Evaluation Report, Acute Oral Toxicity Study in Rats, dated April 23, 1996 (hereinafter referred to as ``BPPD Review - April 23, 1996'')).

2. Acute pulmonary toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3150; MRID 45798201). The Agency required an intratracheal pulmonary infectivity/pathogenicity study. This test involves intratracheal instillation of the test material and post mortem examination of lungs and other organs for clearance.

Three studies were submitted in support of the mammalian acute infectivity/pathogenicity pulmonary guideline: A range finding study and two complete acute pulmonary studies. The dose-range study concluded that 108 cfu/rat would be a suitable test dose level for the acute pulmonary studies [MRID 45739101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as ``BPPD Review - April 02, 2003a'')). In the first acute pulmonary study, conducted with Tween 80 as a surfactant in the test material, 26 male and 26 female Sprague Dawley rats (approximately 8 to 10 weeks old) each were dosed with a single intratracheal dose of 1.2 mL/kg at 5.30 x 108 cfu/mL (or 1.28 to 1.63 x 108 cfu/ animal). Results from this study indicated that the test organism was neither infective nor pathogenic, in spite of rat mortality, which is believed to have been due to a severe acute inflammatory response to the Tween 80 [MRID 45798101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as ``BPPD Review - April 02, 2003b'')].

In the second acute pulmonary study, which was a repetition of the first acute pulmonary test, but was conducted without Tween 80, 25 male and 25 female Sprague Dawley rats (approximately 8 to 10 weeks old) each received a single intratracheal dose of approximately 1.2 mL/kg. Mortality of 4 rats by day 2 appeared to be attributable to an initial dosing effect. The rest of the test animals showed an initial response, followed by a rapid recovery indicating no toxicity. Although some surviving rats lost weight intermittently, all surviving rats gained weight prior to scheduled sacrifice. No clinical signs that were considered to be due to the test organism were observed in the test rats. Organs were examined post mortem as previously described. Aspergillus flavus AF36 was detected in the lungs with clearance by day 8 after dosing. No test organisms were detected in any samples from the shelf control or inactivated test organism treated rats. Based on the presented/submitted data, including the clearance data, the test organism, Aspergillus flavus AF36, was considered not toxic, infective, or pathogenic to the rat pulmonary system. The study is acceptable.

3. Acute inhalation (OPPTS Harmonized Guideline 152-32). The inert is sterilized wheat seeds, comprising approximately 99% of this pesticidal product. It acts as a matrix and nutrient source for the germinating AF36. Because this constitutes the majority of the pesticide and does not contain respirable particles of less than 10 microns, an inhalation study was not required pursuant to 40 CFR 158.740(c). In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, AF36 is considered not toxic, infective, or pathogenic to the rat pulmonary system. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute inhalation effects. [MRID 45798201; BPPD Data Evaluation Report, dated April 02, 2003c (hereinafter referred to as ``BPPD Review - April 02, 2003c'')].

4. Hypersensitivity incidents (OPPTS Harmonized Guideline 152-37; MRID 45739104). The registrant submitted information (MRID 45739104) to

demonstrate the lack of hypersensitivity to workers who have been exposed during the manufacture, application, and use of the pesticide in the research and experimental phases. No adverse hypersensitivity reaction to AF36 was recorded or reported by a state council or six companies during use for 3 or 6 years [MRID 45739104; BPPD Data Evaluation Report, dated April 02, 2003d (hereinafter referred to as ``BPPD Review - April 02, 2003d'')]. However, to comply with the Agency's requirements under section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

5. Data waivers. Data waivers were requested for the following studies:

i. Acute dermal toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3100)

ii. Primary dermal irritation (OPPTS Harmonized Guideline 870.2500)

iii. Primary eye irritation (OPPTS Harmonized Guideline 870.2400)

iv. Intravenous, intracerebral, intraperitoneal injection (OPPTS Harmonized Guideline 885.3200)

v. Hypersensitivity study (40 CFR 152-36)

vi. Immune response (40 CFR 152-38)

With regards to the dermal and eye irritation guideline tests, it was impractical to apply the end-use product, sterilized wheat seeds inoculated with Aspergillus flavus AF36, as test material. Furthermore, non-occupational dermal and eye exposures, or exposures via any of the routes in Unit III.5.i.--vi., are not likely to be above naturally-occurring background levels for the following reasons.

First, Aspergillus flavus, a saprophytic fungus, is a normal

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constituent of the microflora in air and soil. The naturally occurring soil and plant colonizer is also found on living and dead plant material throughout the world. Aflatoxin-producing strains of Aspergillus flavus are particularly prominent in hot, dry climates supplemented with irrigation and are ubiquitous components of the natural Arizona desert ecosystem. Quantities of A. flavus typically increase during crop production and the fungus occurs widely on crop debris left in the soil. Shortly after application, AF36 germinates, apparently displaces the aflatoxin-producing strains from cotton and the soil, and spore levels return to normal background, without increase of total A. flavus. This was demonstrated in soil and air monitoring studies submitted over multiple years of experimental usage [BPPD Review - May 15, 2003]. Thus exposures to AF36 are not likely to increase above those normally associated with the naturally occurring A. flavus background levels.

Second, the application rate is low, being less than 0.01 lb active ingredient per acre, and agricultural sites are treated, thus minimizing non-occupational and residential exposure. The proposed label rate is less than 0.01 pound of active ingredient in 10 pounds end-use product, or approximately 1.34 x 107 colony forming units (cfu) per acre.

Finally, drift is not expected during application based on the large granular nature of the pesticide (i.e., sterilized inoculated wheat seeds). In addition, only one prebloom application is made, and cultivation is not recommended after application. Thus, once again, the potential for non-occupational dermal and residential exposure is unlikely.

The acute oral toxicological study demonstrated an LD₅₀ of greater than 5,000 mg/kg with no toxicity/infectivity effects, and demonstrable clearance from organs examined post mortem [MRID 43972403; BPPD Review - April 23, 1996]. This rationale supported the request to

waive the acute intraperitoneal study.

A hypersensitivity study was waived since hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, A. flavus AF36 [BPPD Review - April 02, 2003d). Nevertheless, reports of hypersensitivity incidents associated with the use of the pesticide are still required to comply with FIFRA section 6(a)(2) requirements.

Submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) also indicate that following oral and pulmonary routes of exposure [BPPD Review - April 23, 1996; BPPD Review - April 02, 2003c), the immune system is still intact and able to process and clear the active ingredient. Thus, the request to waive the immune response study was granted.

On the basis of the foregoing rationales, and there being no documented problems associated with the non-aflatoxin producing strain, Aspergillus flavus AF36, data waivers for the studies listed in Unit III.5.i.--vi., were granted to the applicant for the proposed use of Aspergillus flavus AF36 on cotton.

6. Subchronic, chronic toxicity and oncogenicity, and residue. Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is a potential for aggregate exposure of adult humans, infants and children to the microbe because of the ubiquitous distribution of Aspergillus fungal strains in the environment. The Agency has considered the incremental exposure and risk associated with the proposed application of this strain of Aspergillus flavus, AF36, as summarized below, and concludes that use of AF36 is not likely to add an incremental risk above that posed by the normal exposure of adults, infants and children to Aspergillus flavus strains present in the environment. In fact, use of the pesticide, AF36, may decrease potential environmental aflatoxin exposure to exposed populations.

A. Dietary Exposure

1. Food. Based on submitted studies, the end-use product, Aspergillus flavus AF36, demonstrates low acute oral toxicity category IV potential [BPPD Review - April 23, 1996). No toxicity endpoints were indicated to justify setting a numerical tolerance for the fungal active ingredient, Aspergillus flavus AF36. An LD₅₀ greater than 5,000 mg/kg body weight, in the acute oral studies discussed above, indicates that consumption of food commodities treated with AF36 poses no incremental risk via dietary exposure. Indeed, the submitted data indicate no toxicity or infectivity of AF36 in the acute oral test mammalian systems.

Cotton itself is not a food commodity. Residues of A. flavus AF36, the microbial active ingredient, are not likely to survive the heating and pressure associated with the processing of cottonseed into

cottonseed meal. Moreover, A. flavus AF36 will not separate into the edible fraction, cotton seed oil. Thus, potential transfer of residues of A. flavus AF36 to edible cotton food/feed commodities is not expected. Consequently, human dietary exposure to A. flavus AF36 via cottonseed oil, or by secondary transfer of A. flavus AF36 residues to meat and milk via cottonseed meal, is not expected. Therefore, the Agency has determined that dietary exposure to A. flavus AF36 is not likely to result in any undue health effects and risk.

While the Agency has concluded that AF36 is not likely to add to the dietary burden, any potential contribution by AF36 to aflatoxin contamination was also considered, for a conservative estimate of the health effects of this pesticide. This is because aflatoxin is considered a public health hazard (see Unit VII.D.) and AF36 is proposed as a biocontrol agent for aflatoxin-producing strains of A. flavus. Even if AF36 does not control aflatoxin levels in the treated cotton food/feed commodities, a safety net exists in the screening of cotton and its by-products for aflatoxin prior to their introduction into the channels of commerce. For instance, FDA does not allow cotton seed products containing aflatoxin above 20 parts per billion (ppb) to be used in dairy rations or above 300 ppb to be used for feeding beef cattle. As previously stated, the registrant claims that quality control and selection procedures will not allow aflatoxin production in the starter cultures for pesticide manufacture [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Any batches with aflatoxin are to be destroyed. For these reasons, the Agency has determined that use of AF36 will not add to the dietary burden of aflatoxin, but is rather more likely to ameliorate aflatoxin levels in treated cotton food/feed commodities. Therefore, dietary exposure to aflatoxin, as a result of AF36 use, is not likely to be greater, and may even be less, than that which currently exists.

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2. Drinking water exposure. Exposure to AF36 via drinking water is not likely to be greater than current/existing exposures to A. flavus strains. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, percolation through soil. Thus, exposure via drinking water from the proposed use of this non-aflatoxin-producing strain of Aspergillus flavus is not likely to pose any incremental risk to adult humans, infants and children. In fact, displacement of the toxigenic strains of A. flavus by AF36 may decrease exposure and risk to the toxigenic strains of A. flavus in the environment.

B. Other Non-Occupational Exposure

1. Dermal exposure. The potential for non-occupational dermal exposure to AF36 is unlikely because the potential use sites, are commercial and agricultural, and because of the granular nature of the pesticide, which minimizes spray drift. As discussed earlier (see Unit III.), lack of hypersensitivity incidents, low application rates, and return of levels of Aspergillus flavus to background shortly after germination, poses minimal risk to populations via dermal, non-occupational exposure. Thus, dermal non-occupational exposure to the non-aflatoxin strain is not likely to be greater than the existing exposure to A. flavus at current levels.

2. Inhalation exposure. For the reasons stated immediately above, non-occupational inhalation exposure to AF36 is not expected to be greater than that which currently exists for A. flavus strains.

V. Cumulative Effects

chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of this active ingredient, Aspergillus flavus AF36, at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an ``endocrine disrupter'' produced by this microorganism. The submitted toxicity/infectivity or pathogenicity studies in the rodent (required for microbial pesticides) indicate that, following oral and pulmonary routes of exposure, the immune system is still intact and able to process and clear the active ingredient (see Unit III.). In addition, based on the low potential exposure level associated with the proposed single, seasonal, prebloom application of the pesticide, the Agency expects no adverse effects to the endocrine or immune systems.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly, the Agency has concluded that for an exemption from tolerance, analytical methods are not needed for enforcement purposes for residues of Aspergillus flavus AF36 on treated cotton. Nonetheless, and for purposes of clarification, analytical methods are still required for product characterization, quality control, and quality assurance for manufacturing purposes [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Vegetative compatibility tests are used to screen starter cultures to identify the non-aflatoxin-producing Aspergillus flavus AF36 strain. Starter cultures of AF36 are also selected on the basis of

([Page 41540])

the lack of aflatoxin as monitored by standard thin layer chromatography (tlc) procedures and visualization via scanning fluorescence densitometry scanning. Other appropriate methods are required for quality control to assure product characterization, the control of human pathogens and other unintentional metabolites or ingredients within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of Aspergillus flavus AF36.

D. Efficacy Data

PR Notice 2002-1 lists aflatoxin as a public health hazard, for which product performance or efficacy data are required according to 40 CFR 158.202(i). To demonstrate that this pesticide may reduce aflatoxin-producing strains and does not increase A. flavus populations above background levels, the applicant provided product performance or efficacy data from multiple years of soil and air monitoring studies.

Aflatoxin, one of the most potent human carcinogens, is the metabolite of concern produced by the target pest, aflatoxin-producing strains of Aspergillus flavus. As such, the Agency considers aflatoxin

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to Aspergillus flavus AF36 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Aspergillus flavus AF36 does not appear to be toxic or pathogenic to humans. There is no indication that the fungus A. flavus AF36 shares any common mechanisms of toxicity with other registered pesticides. In addition, there are no other registered pesticide products containing Aspergillus flavus AF36, and other A. flavus strains abound naturally in the environment. Moreover, the displacement of the toxigenic strain of A. flavus by AF36 may reduce aflatoxin contamination of cottonseed. Based on the low toxicity potential of AF36, the fact that it is non-aflatoxigenic, and the safety net already in place to monitor for aflatoxin, no cumulative or incremental effect is expected from the use of AF36 on cotton.

VI. Determination of Safety for U.S. Population, Infants and Children

There is reasonable certainty that no harm will result from aggregate exposures to residues of A. flavus AF36, in its use as an antifungal agent, to the U. S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this fungus in its use as an antifungal agent via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Unit III above). Moreover, non-occupational inhalation or dermal exposure is not expected above background levels (see Unit V).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that the fungus, A. flavus AF36, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when A. flavus AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of A. flavus AF36.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ``may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen-and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide

a public health hazard. In the soils of cotton-producing areas of Arizona and south Texas, especially in the dry regions, the toxigenic strains are prominent. Few alternatives, if any, exist to displace aflatoxin-producing A. flavus strains from cotton and other crops. Decontamination of crops via ammoniation is costly, not available universally, and decreases the value of the crop. Other methods to reduce aflatoxin formation include manipulation of harvest date, costly irrigation practices, and different methods of harvesting and storage practices.

Efficacy data submitted to the Agency include monitoring of soil and air levels of the toxigenic and non-aflatoxin-producing strains of A. flavus AF36 in the field and on the crops. Results from the environmental expression and population monitoring studies, during the experimental program, demonstrate that a single seasonal application of AF36 on cotton fields may incite significant changes in the incidence of toxigenic A. flavus strains resident in the agroecosystem, without altering the overall quantity of A. flavus. Soil and air population counts of A. flavus from treated fields were associated with concomitant decreases in incidences of toxigenic A. flavus, for many of the treated areas [BPPD review - May 15, 2003]. Reducing the aflatoxin-producing populations of fungi, and the concomitant reduction of aflatoxin, a potent carcinogen, is in the public interest.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ``object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0138 in the subject line on the first page of your submission. All objections and hearing requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 12, 2003.

1. Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be

disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ``Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ``when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at <A HREF="mailto:tompkins.jim@epa.gov">tompkins.jim@epa.gov</A>, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0138, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit

([Page 41541])

I.B.1. You may also send an electronic copy of your request via e-mail to: <A HREF="mailto:opp-docket@epa.gov">opp-docket@epa.gov</A>. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought

by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption from the tolerance requirement in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ``meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ``Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ``substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ``tribal implications'' as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ``meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ``Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ``substantial direct effects on one or more Indian tribes, on the relationship between the Federal

Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a ``major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 2, 2003.
James Jones,
Director, Office of Pesticide Programs.

• Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED)

• 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

• 2. Section 180.1206 is revised to read as follows:

Sec. 180.1206 Aspergillus flavus AF36; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide Aspergillus flavus AF36 in or on cotton and its food/feed commodities.

[FR Doc. 03-17726 Filed 7-11-03; 8:45 am]
BILLING CODE 6560-50-S

For problems with this list, contact epa-pest-Owner@lists.epa.gov
---

Michael Braverman
<braverman@AESOP.Rutgers.edu>

To: Chris Pfeifer/DC/USEPA/US@EPA, jinouye@cdpr.ca.gov
cc: Shanaz Bacchus/DC/USEPA/US@EPA
Subject: FW: CA counties needing AF36/cotton

07/14/2004 03:14 PM

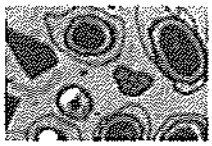
Chris and John

Sorry I didn't copy you on this.

Shanaz our e-mails crossed.....

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
http://ir4.rutgers.edu/

BIOPESTICIDES


MICROBIALS


PHEROMONES


NATURAL PRODUCTS

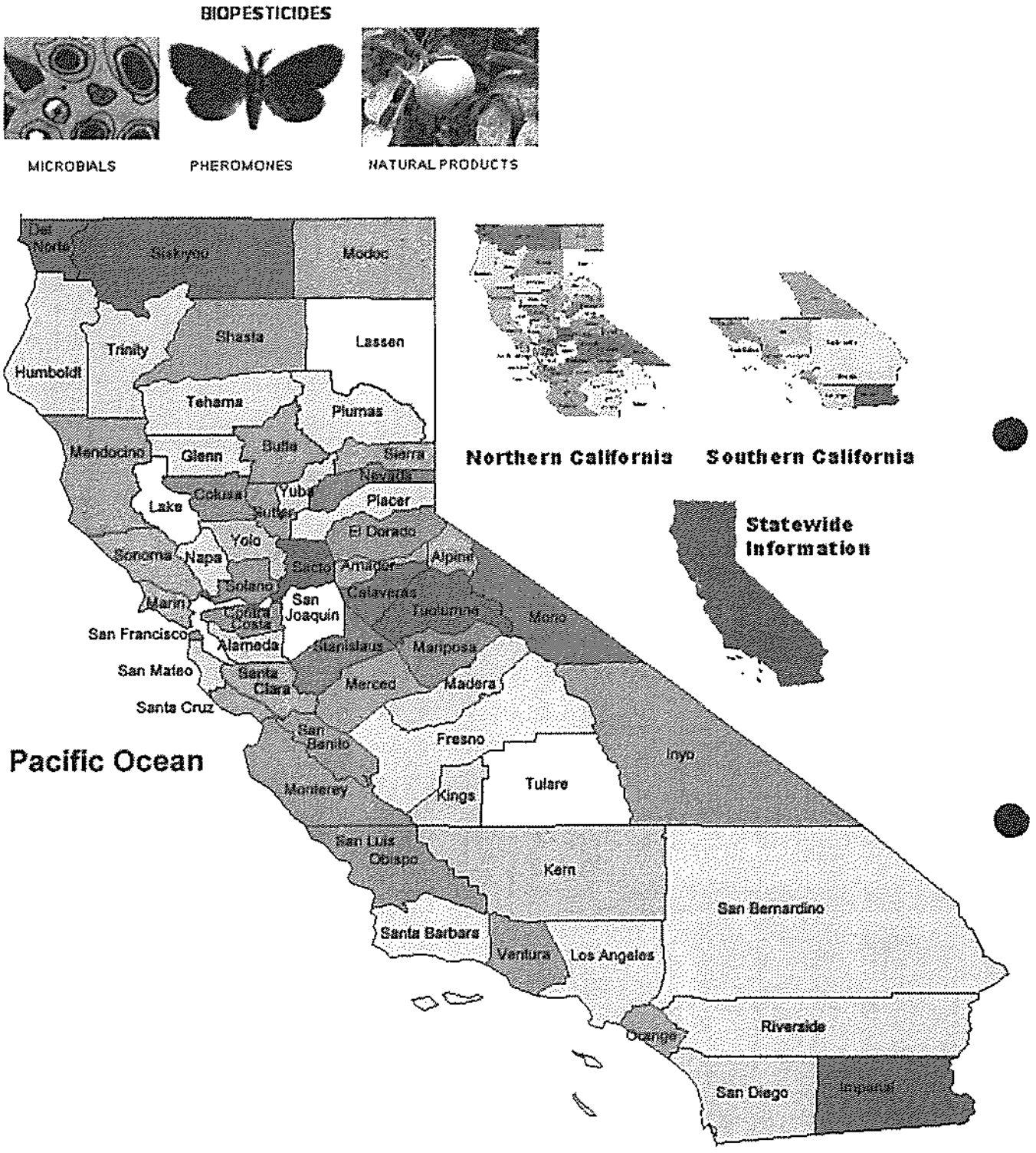
-----Original Message-----
From: Michael Braverman [mailto:braverman@aesop.rutgers.edu]
Sent: Wednesday, July 14, 2004 1:55 PM
To: Shanaz Bacchus (Bacchus.Shanaz@epamail.epa.gov)
Cc: Peter Cotty; Larry Antilla (LAntilla@AZcotton.com); Phil Wakelyn (pwakelyn@cotton.org)
Subject: FW: CA counties needing AF36/cotton

Shanaz

I spoke to Peter. The counties AF36 are likely to be used-needed in for cotton are Imperial, Riverside and San Bernadino. A map of California counties is below. These 3 counties are in the southern part of California adjoining Arizona. Per county cotton production information is also listed below . Please let me know if you need hard copies of this.

Thanks

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
http://ir4.rutgers.edu/



CALIFORNIA COTTON, UPLAND: Acreage, Yield And Production By

planted.

Return to: [Table of Contents for County Estimates] [CASS Publications] [CASS Homepage] [Questions?]

California Agricultural Statistics Service
P.O. Box 1258
Sacramento, CA 95812
Phone: (916) 498-5161
Fax: (916) 498-5186
E-mail: nass-ca@nass.usda.gov

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
http://ir4.rutgers.edu/

County, 2003 Preliminary					
County	Planted	Harvested	Yield/Acre	Production	
	Acres			*Pounds*	*Bales*
Del Norte	---	---	---	---	
Humboldt	---	---	---	---	
Mendocino	---	---	---	---	
District 10 Total	---	---	---	---	
Shasta	---	---	---	---	
Siskiyou	---	---	---	---	
Trinity	---	---	---	---	
District 20 Total	---	---	---	---	
Lassen	---	---	---	---	
Modoc	---	---	---	---	
Plumas	---	---	---	---	
District 30 Total	---	---	---	---	
Alameda	---	---	---	---	
Contra Costa	---	---	---	---	
Lake	---	---	---	---	
Marin	---	---	---	---	
Monterey	---	---	---	---	
Napa	---	---	---	---	
San Benito	---	---	---	---	
San Francisco	---	---	---	---	
San Luis Obispo	---	---	---	---	
San Mateo	---	---	---	---	
Santa Clara	---	---	---	---	
Santa Cruz	---	---	---	---	
Sonoma	---	---	---	---	
District 40 Total	---	---	---	---	
Butte	---	---	---	---	
Colusa	4,700	4,400	1,364	12,500	
Glenn	2,100	1,800	1,067	4,000	
Sacramento	---	---	---	---	
Solano	---	---	---	---	
Sutter	1,500	1,400	1,063	3,100	
Tehama	---	---	---	---	

Yolo	---	---	---	---	
Yuba	---	---	---	---	
Other Counties 1/	100	100	960	200	
District 50 Total	**8,400**	**7,700**	**1,234**	**19,800**	
Fresno	188,000	187,000	1,325	516,100	
Kern	91,400	91,000	1,333	252,800	
Kings	94,100	93,400	1,295	252,000	
Madera	18,500	18,000	1,200	45,000	
Merced	70,400	70,000	1,247	181,900	
San Joaquin	---	---	---	---	
Stanislaus	---	---	---	---	
Tulare	58,500	57,600	1,346	161,500	
Other Counties 1/	200	200	960	400	
District 51 Total	**521,100**	**517,200**	**1,308**	**1,409,700**	
Alpine	---	---	---	---	
Amador	---	---	---	---	
Calaveras	---	---	---	---	
El Dorado	---	---	---	---	
Inyo	---	---	---	---	
Mariposa	---	---	---	---	
Mono	---	---	---	---	
Nevada	---	---	---	---	
Placer	---	---	---	---	
Sierra	---	---	---	---	
Tuolumne	---	---	---	---	
District 60 Total	---	---	---	---	
Imperial	6,100	5,900	1,554	19,100	
Los Angeles	---	---	---	---	
Orange	---	---	---	---	
Riverside	13,500	13,400	1,587	44,300	
San Bernardino	900	800	1,260	2,100	
San Diego	---	---	---	---	
Santa Barbara	---	---	---	---	
Ventura	---	---	---	---	
District 80 Total	**20,500**	**20,100**	**1,564**	**65,500**	
STATE	**550,000**	**545,000**	**1,317**	**1,495,000**	

1/ Includes one or more counties within a district that normally have less than 500 acres

dpr Department of Pesticide Regulation

Paul Gosselin
Acting Director

Arnold Schwarzenegger
Governor

July 13, 2004

71693-1

Ms. Shanaz Bacchus
Biopesticides and Pollution Prevention Division
OPP (7504C)
U.S. EPA
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Ms Bacchus:

AF36 Cotton Review Memos

Per Michael Braverman, enclosed are copies to our review memos.

If you should have any questions, please call me.

Sincerely,

John E. Inouye

John E. Inouye
Senior Pesticide Use Specialist
Registration Branch
(916) 324-3538

cc: Dr. Michael Braverman, IR-4 Project, Rutgers University

State of California Department of Pesticide Regulation

EVALUATION REPORT - PESTICIDE

Date: April 1, 2004

ID	: 205526-N
EPA Reg No	: 71693-1 (new a.i.)
Applicant	: IR-4
Registrant	: Arizona Cotton Research and Protection Council
Active Ingredient	: *Aspergillus flavus* strain AF36
Use	: Fungicide
Registration Action	: Section 3
Area of Review	: Fish and Wildlife (Endangered Species)

Registration Specialist: John Inouye

[X] Data support registration

[ ] Data does not support registration

[ ] No registration action required

SUMMARY: In accordance with Title 3, Section 6206 of the California Code of Regulations (CCR), the director is considering a petition by the Interregional Research Project Number 4 (IR-4) for Section 3 registration of a non-aflatoxin producing strain of *Aspergillus flavus* on cotton to control aflatoxin-producing strains of *Aspergillus flavus* on cotton. The proposed use calls for surface broadcast treatments of cultures grown on wheat.

Pursuant to CCR Sections 6158(d) and 6206, this review considers use limitations to mitigate adverse effects to non-target organisms with particular attention to protection of federally listed species.

TOXIC POTENTIAL: *Aspergillus flavus* is ubiquitous in the environment and is exempt from tolerance. Fish and wildlife hazard data has been waived by USEPA because the proposed use will not significantly increase the naturally occurring populations of *A. flavus*.

CONCLUSION: There is a low probability of exposure to fish and wildlife generally from the proposed use in cotton and low toxic potential indicated by natural occurrence of the organism and waivers of toxicology data requirements. Due to low toxic potential and low probability of exposure, use of this product per label directions is not likely to pose risks to fish or wildlife in general nor to listed species in particular.

INOUYE

State of California Department of Pesticide Regulation

EVALUATION REPORT – PESTICIDE

Date: May 20, 2004

Microbiology – Hanna Daoud

Product Name	:	*Aspergillus flavus* AF36
I.D. No.	:	205526-N
Applicant	:	Arizona Cotton Research and Protection Council
EPA Reg. No.	:	71693 - 1
Document No.	:	52965 - 0001, - 0002, - 0012
Active Ingredient	:	*Aspergillus flavus* strain AF36
Use	:	For displacing aflatoxin-producing-fungi on cotton
Registration Action	:	Section 3 / New Active Ingredient
Area of Review	:	Microbiology

Registration Specialist : Gary Sprock / John Inouye

[ ] Data/Information Support Registration

[x] Data/Information Support Conditional Registration

[ ] Data/Information Do Not Support Registration

[ ] No Registration Action Required

Summary:

On behalf of the Arizona Cotton Research and Protection Council, the Interregional Research Project No.4 (IR-4), submitted an application for the registration of the Microbial Pest Control Agent (MPCA) *Aspergillus flavus* AF36, EPA Reg. No. 71693-1 for displacing/reducing aflatoxin-producing strains of *Aspergillus flavus* on cotton in California.

Aspergillus flavus AF36 is a solid granular end-use product formulation containing 0.0008% by weight (3000 CFU/g) *Aspergillus flavus* strain AF36, a non-aflatoxin-producing (atoxigenic) strain of the fungus *Aspergillus flavus*, as the active ingredient.

The product is to be broadcast on soil surface as a prebloom application once a year either by ground application or by aerial application at the rate of 10 pounds end-use product (which is equivalent to 0.0008 pound of active ingredient) per acre. The product label recommends that the colonized wheat seeds (the end-use product) not be covered with soil, and it cautions that cultivation after aerial and ground application may diminish product efficacy. The label also recommends that within 3 days of application, the fields are to be irrigated to promote germination of the fungal strain AF36 which is expected to colonize the cotton crop and soil before the aflatoxin-producing strains of *Aspergillus flavus* proliferate, thus, reducing aflatoxin contamination of cotton and cotton seeds.

The product has been conditionally registered by the U.S.EPA for this use on cotton in the states of Arizona and Texas only, effective June 24, 2003. This conditional registration is contingent upon compliance with the conditions and timeframes specified in EPA's Notice of Conditional Registration dated June 24, 2003.

Now, the registrant, Arizona Cotton Research and Protection Council, is seeking to add the state of California to the EPA's registered label and has submitted information on Product Chemistry/Microbiology to address the following:

- Product Identity and Composition (Record No. 209910, Document No. 52965-0012).
- Manufacturing Process and Quality Control (Record No. 209911, Document No. 52965-0012).
- Discussion on Formulation of Unintentional Ingredients (Record No. 209912, Document No. 52965-0012).
- Analytical Methods.
- Certified limits (per EPA's CSF).
- U.S.EPA's "Biocide Registration Action Document for *Aspergillus flavus* AF36 (PC Code 006456)". (DPR Record No. 209899, Document No. 52965-0001).

The submitted data/information have been reviewed and a number of deficiencies have been identified. These deficiencies are outlined in the "Conclusion" portion of this report.

It is to be noted that these deficiencies have also been identified in U.S.EPA review of the subject product and were made conditions for the existing EPA Conditional Registration in the states of Arizona and Texas. They will also be applicable to California.

Discussion:

Based on the information provided, the subject product, *Aspergillus flavus* AF36, is an end-use product. This end-use product basically consists of sterile wheat seeds that have been colonized by the fungus *Aspergillus flavus* strain AF36, a non-aflatoxin-producing (atoxigenic) strain of *Aspergillus flavus* which constitutes the active ingredient in the product. The sterile wheat seed serve as a carrier and as a nutrient source for the living fungus.

The product label and CSF show the product contains 0.0008% by weight (3000 CFU/g) *Aspergillus flavus* strain AF36 as the active ingredient. Analytical data demonstrating/ substantiating this claimed value for the active ingredient in the product have not been provided.

Aspergillus flavus strain AF36, the active ingredient in the subject product, is said to be a naturally occurring (not genetically modified) atoxigenic strain of *Aspergillus flavus* whose species are ubiquitous worldwide. It was isolated from cottonseed collected in the Yuma Valley of Arizona. The isolate has been deposited at the American Type Culture Collection under the

accession numbers ATCC – 96045 and ATCC – 96047. It is reported to be distinguishable from aflatoxin-producing *Aspergillus flavus* strains by vegetative compatibility analysis. It is not clear whether this analytical method is capable of distinguishing strain AF36 from other strains of *Aspergillus flavus* including other non-aflatoxin-producing strains.

Strain AF36 has been characterized as an "atoxigenic" strain of *Aspergillus flavus* for its lack of aflatoxin production. Aflatoxin is a potent carcinogen produced by toxigenic strains of *Aspergillus flavus*. Its levels in cotton and cotton byproducts, cottonseed oil and cottonseed meal, are regulated by the FDA.

It is to be noted that the inability to produce aflatoxin does not necessarily mean the inability to produce other mycotoxins or other harmful or undesirable metabolites. Therefore, the capacity of strain AF36 to produce other metabolites needs to be assessed.

Detailed description of the manufacturing process and a brief discussion of the quality control program employed during the manufacturing process, as well as a brief discussion on the formation of unintentional ingredients have been provided. However, supporting data from sample analysis and quality control tests demonstrating product purity, quality and integrity were not provided. Also not provided are the quality control standards (acceptance/rejection limits) to be employed in the production process. Also, data from storage stability study were not provided.

A temporary exemption from the requirement of a residue tolerance of *Aspergillus flavus* AF36 on cotton was established in 40 CFR 180.1206 in conjunction with the Experimental Use Permit 69224 EUP-1 in Arizona, with an expiration date of December 30, 2003. For the current EPA 3(C)(7)(C) conditional registration in Arizona and Texas, a permanent tolerance exemption is being established in 40 CFR 180.1206 for residue of *Aspergillus flavus* AF36 on cotton when used as labeled as a prebloom application.

Aspergillus flavus AF36 exemption from the requirement of a residue tolerance negates the need for a residue-enforcement analytical method. However, analytical methods for product characterization and quality control during the manufacturing process and for product quality enforcement at the marketing level are still required.

Due to the nature and composition of this microbial product, many of the physical and chemical properties required of chemical pesticides, including pH, melting point, boiling point, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, oxidizing or reducing potential, flammability/flash point, explodability, viscosity, corrosion characteristics, and dielectric breakdown voltage, are not applicable to this product; therefore, they are not required.

Competitive exclusion is reported to be the mode of action or mechanism by which strain AF36 replaces aflatoxin-producing *Aspergillus flavus* strains. Upon application, the level of strain AF36 increases during the postapplication germination phase, but this increase returns to normal within a few weeks.

The displacement of the aflatoxin-producing strains by strain AF36 does not appreciably change the total *Aspergillus* population. However, it may reduce the aflatoxin-producing strains and thereby reduces aflatoxin contamination of cotton seed. Even if AF36 does not control or reduce aflatoxin levels in treated cotton seed, it is not likely to increase it to above normal background levels.

The application of a single, seasonal, prebloom application at the proposed low rate of 10 pounds end-use product (equivalent to less than 0.01 pound active ingredient) per acre is not likely to appreciably change the overall quantity of *Aspergillus flavus* spores in the environment, or to increase aflatoxin to above normal background levels within the range of natural variation in cotton seed or in the environment. Therefore, its impact on the environment, if any, is likely to be minimal or negligible.

In its review as expressed in EPA "Biocide Registration Action Document", the U.S.EPA found *Aspergillus flavus* AF36 to be eligible for a conditional registration, and that its proposed use on cotton in Arizona and Texas to be in the "public interest", and that AF36 is not likely to pose undesirable risk to health or the environment, and that certain conditions apply to this eligibility and the applicant must take certain action (e.g. generate and provide certain data) within the timeframe outlined in section VI titled "Action Required by Registrant" (page 45 of 55 pages, Record No. 209899).

Also in its "Public Interest Finding", the U.S.EPA indicated that the Agency believes the use of AF36 under this conditional registration would be in the public interest according to the criteria for public interest outlined in 51 FR No.43, Wednesday March 5, 1986. And stated that: "The Agency has determined that the conditional registration of the indigenous *Aspergillus flavus* AF36 is likely to provide a cost effective biocontrol agent for reduction of aflatoxin in cotton and its food/feed by products, and is in the public interest." (Pages 38 of 55 pages, U.S.EPA Biocide Registration Action Document for *Aspergillus flavus* AF36, Record No. 209899).

Conclusion:

The submitted data and information support a conditional registration of the subject product for the proposed use on cotton in California, provided the applicant agrees to submit the following required data/information within one year from the date the conditional registration becomes effective:

1. Results of five-batch analysis study demonstrating:
    a. Number of colony forming units (CFU) of *Aspergillus flavus* strain AF36 per gram product.
    b. Certification of limits.
    c. Identity and number of potential microbial contaminants (human pathogens).
    d. Identity and quantity of metabolites and other unintentional ingredients.
2. Storage stability.
3. Quality control standards (acceptance/rejection limits) for the active ingredient, potential microbial contaminants, harmful metabolites, if any, and other unintentional ingredients that may be present in the product.
4. Method for identifying/distinguishing strain AF36 from other strains of *Aspergillus flavus* (including other non-aflatoxin-producing strains) other than the vegetative compatibility method.
5. An enforcement analytical method for purposes of enforcing product quality at the market-place level.

Hanna Daoud

Hanna Daoud, Ph.D.
Senior Environmental Research Scientist

Pages 62-66 Confidential Statement of Formula may be entitled to confidential treatment